

Memorandum

Date

From

Thomas D. Roslewicz

Deputy Inspector General

for Audit Services

Subject

To

Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Department of Health and Human Resources (A-06-01-00007)

Neil Donovan
Director, Audit Liaison Staff
Centers for Medicare & Medicaid Services

This memorandum is to alert you to the issuance on December 31, 2001, of our final report entitled, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Department of Health and Human Resources." A copy of the report is attached. We suggest you share this report with components of the Centers for Medicare & Medicaid Services involved with program integrity, provider issues, and State Medicaid agency oversight, particularly the Center for Medicaid and State Operations.

Most States use average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions. Therefore, the objective of this review was to develop for the West Virginia Medicaid program an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs.

Through use of statistical sampling, we obtained from West Virginia retail pharmacies 2,728 invoice prices for brand name drugs, and 1,507 invoice prices for generic drugs. Our estimate of the overall discount below AWP for the invoice prices we reviewed was 21.71 percent for brand name drugs and 68.92 percent for generic drugs. Our national estimates, included in reports we previously issued to you¹, were 21.84 percent and 65.93 percent, respectively. The estimates combined the results for four categories of pharmacies, including rural-chain, rural-independent, urban-chain, and urban-independent. The estimates excluded the results obtained from non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, home IV, etc.) because we believe such pharmacies are able to purchase drugs at substantially greater discounts than retail pharmacies and including those discounts would inflate our estimates.

We recommended that the West Virginia Department of Health and Human Resources (State Agency) consider the results of our review as a factor in determining any future

¹ Final report dated August 10, 2001 entitled, "Medicaid Pharmacy-Actual Acquisition Cost of Brand Name Prescription Drug Products (A-06-00-00023)." Draft report dated August 20, 2001 entitled, "Medicaid Pharmacy-Actual Acquisition Cost of Generic Prescription Drug Products (A-06-01-00053)."

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changes to pharmacy reimbursement for Medicaid drugs. The State Agency was appreciative of our report and stated that it was considering adjusting the discount of AWP to more correctly reflect the prices pharmacies are actually paying for prescription drugs.

Any questions or comments on any aspect of this memorandum are welcome. Please address them to George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104 or Gordon L. Sato, Regional Inspector General for Audit Services, Region VI, at (214) 767-8414.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES



JANET REHNQUIST Inspector General

DECEMBER 2001 A-06-01-00007

DEPARTMENT OF HEALTH & HUMAN SERVICES





Office of Audit Services 1100 Commerce, Room 6B6 Dallas, TX 75242

Common Identification Number: A-06-01-00007

Nancy V. Atkins, MSN, RNC, NP Commissioner Department of Health and Human Resources 350 Capitol Street, Room 251 Charleston, West Virginia 25301

Dear Ms. Atkins:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) final report entitled, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Department of Health and Human Resources." A copy of this report will be forwarded to the action official noted below for review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, OAS reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR part 5). As such, within 10 business days after the final report is issued, it will be posted on the world wide web at http://www.oig.hhs.gov.

To facilitate identification, please refer to common identification number A-06-01-00007 in all correspondence relating to this report.

Sincerely yours.

Gordon L. Sato

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Regional Inspector General for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Steven McAdoo Acting Regional Administrator Centers for Medicare & Medicaid Services 150 S. Independence Mall West, Suite 216 Philadelphia, Pennsylvania 19106

SUMMARY

As a follow-up to our previous work, the Office of Inspector General conducted a nationwide review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. Most States use average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions. Therefore, the objective of this review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs.

To accomplish our objective, we selected a stratified random sample of 8 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. West Virginia was one of the sample States selected, as well as Colorado, Florida, Indiana, Montana, Texas, Washington, and Wisconsin.

In addition, a random sample of Medicaid provider pharmacies from each State was selected. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, home IV, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our overall estimates. We believe such pharmacies are able to purchase drugs at substantially greater discounts than retail pharmacies, and including those discounts would inflate our estimates.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between invoice price and AWP for each category.

In West Virginia, we obtained drug pricing information from 37 pharmacies (including non-traditional). Specifically, we obtained 2,728 invoice prices for brand name drugs, and 1,507 invoice prices for generic drugs (excluding non-traditional). For West Virginia, our estimate of the overall discount below AWP for the invoice prices we reviewed was 21.71 percent for brand name drugs and 68.92 percent for generic drugs. The national estimates were 21.84 percent and 65.93 percent, respectively. Our previous estimates, based on Calendar Year 1994 pricing data, were 18.30 percent and 42.45 percent, respectively. The estimates combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and excluded the results obtained from non-traditional pharmacies.

We recommended that the West Virginia Department of Health and Human Resources (State Agency) consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs. The State Agency responded to our draft report in a letter dated October 18, 2001. The State Agency was appreciative of our report and stated that they were considering adjusting the discount of AWP to more correctly reflect the prices pharmacies are actually paying for prescription drugs.

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INTRODUCTION

The Office of Inspector General (OIG) conducted a review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the West Virginia Department of Health and Human Resources (State Agency). The objective of this review was to develop an estimate of the discount below the average wholesale price (AWP) at which pharmacies purchase brand name and generic drugs. This review was conducted as a part of a nationwide review of pharmacy acquisition costs. West Virginia was one of eight States randomly selected as part of the nationwide review. (See **APPENDIX 3** for the results of our nationwide sample.)

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by the Centers for Medicare & Medicaid Services (CMS). If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less a percentage discount. The AWP is the price assigned to the drug by its manufacturer and is compiled by the **Red Book**, **First DataBank**, and **Medi-Span** for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, the OIG issued a report in 1984, which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, the OIG issued a follow-up report that found that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, CMS issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual issuance further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In 1997, OIG issued separate reports on the actual acquisition cost of brand name and generic drugs. The 1997 reports were based on comparisons of 18,973 invoice prices for brand name products and 9,075 invoice prices for generic products. The reports showed average discounts of 18.30 percent below AWP and 42.45 percent below AWP, respectively. Medicaid drug program expenditures in Calendar Year (CY) 1994 totaled about \$9.4 billion. In CY 1999, nationwide drug expenditures for the program increased to about \$17.9 billion. West Virginia reported Medicaid drug expenditures of \$198 million in CY 1999.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between AWP and the actual invoice prices of both brand name and generic prescription drugs to Medicaid pharmacy providers. Our objective did not require that we identify or review any internal control systems.

Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription for instances such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid-specific administrative costs, and general overhead.

We obtained a listing of all Medicaid pharmacy providers from the State Agency. The State Agency was responsible for classifying each pharmacy as chain, independent, or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a 1999 listing of metropolitan statistical areas and their components. We selected a stratified random sample of 40 pharmacies from a universe of 478 pharmacies, with 8 pharmacies selected from each of 5 strata--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believe that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and including those discounts would inflate our estimates.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1999. Supply sources include wholesalers, chain warehouse distribution centers, generic distributors, and manufacturers. Each pharmacy was initially assigned a month from January 1999 through December 1999 in order to provide a cross-section of this 12-month time period. However, we permitted some pharmacies to provide invoices from other months in 1999, if invoices were not available for the requested period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that the invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We attempted to obtain NDCs in those instances. We used the **2000 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs and identify over-the-counter items. Two prominent wholesalers, as well as four chain stores, whose invoices contained the wholesaler item number rather than NDCs, provided us with a listing that converted their item numbers to an NDC. If we were unable to identify the NDC for a drug, we eliminated the drug.

To verify the drug name, we utilized the drug product file on the CMS web site. In addition to verifying the drug name, we were also able to determine the drug-type indicator from this file.

The drug-type indicator showed whether the drug was a brand name or generic drug. We considered single source and innovator multiple source drugs as brand name drugs. Non-innovator drugs were classified as generic drugs.

We obtained a drug pricing file from **First DataBank** through the State of Florida for the purpose of obtaining the AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file, we eliminated that drug.

We used OIG Office of Audit Services (OAS) statistical software to calculate all estimates as well as to generate all random numbers. We obtained the total number of pharmacies in the universe from the National Council for Prescription Drug Programs. We did not independently verify any information obtained from third-party sources. Additionally, we did not attempt to identify any special discounts, rebates, or other types of special incentives not reflected on the invoices. Our review was conducted by our Little Rock, Arkansas OAS field office from July 2000 through June 2001. (See **APPENDIX 1** for a description of our sample.)

FINDINGS

BRAND NAME DRUGS

We estimated that the invoice price for brand name drugs was 21.71 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 2,728 invoice prices received from 29 pharmacies. The standard deviation for this estimate was 0.52 percent (see **APPENDIX 2**).

The estimates by individual categories for brand name drugs are summarized in the following table:

Estimated Difference Between AWP and Invoice Price for Brand Name Drugs

Category	Percent Below AWP (Point Estimate)	Standard Deviation	Sample Pharmacies	Drug Prices Reviewed
Rural-Chain	22.43	3.16	6	808
Rural-Independent	21.44	0.88	8	369
Urban-Chain	21.88	2.64	8	1,132
Urban-Independent	19.99	2.69	7	419
Non-Traditional	23.86	16.69	7	228
Overall (Exc. Non-Trad.)	21.71	0.52	29	2,728

GENERIC DRUGS

We estimated that the invoice price for generic drugs was 68.92 percent below AWP. Once again, the estimate combined all pharmacy categories except non-traditional pharmacies. The estimate was based on the comparison to AWP of 1,507 invoice prices received from 29 pharmacies. The standard deviation for this estimate was 1.84 percent (see **APPENDIX 2**). The following table summarizes the results by category for generic drugs:

Estimated Difference Between AWP and Invoice Price for Generic Drugs

	101 (1	eneric Drugs		
Category	Percent Below AWP (Point Estimate)	Standard Deviation	Sample Pharmacies	Drug Prices Reviewed
Rural-Chain	73.48	7.51	6	462
Rural-Independent	68.47	5.94	8	185
Urban-Chain	70.29	10.52	8	689
Urban-Independent	54.94	21.99	7	171
Non-Traditional	61.38	14.82	8	152
Overall (Exc.Non-Trad.)	68.92	1.84	29	1,507

CONCLUSIONS AND RECOMMENDATION

Based on our review, we determined that there was a significant difference between AWP and pharmacy acquisition costs. The difference between AWP and pharmacy acquisition costs was significantly greater for generic drugs than for brand name drugs. We recognize that acquisition cost is just one factor in pharmacy reimbursement policy and that any change to that policy should also consider the other factors discussed in the **SCOPE** section of our report.

Additionally, the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations should be taken into consideration. However, a change in any of the factors affecting pharmacy reimbursement could have a significant impact on expenditures because of the size of the program. We believe that the difference between AWP and pharmacy acquisition costs as determined by our review was significant enough to warrant consideration by the State in any evaluation of their Medicaid drug program. Therefore, we recommended that the State Agency consider the results of this review as a factor in determining any future changes to pharmacy reimbursement for Medicaid drugs.

STATE AGENCY'S COMMENTS

The State Agency responded to our draft report in a letter dated October 18, 2001. The State Agency was appreciative of our report and stated that they were considering adjusting the discount of AWP to more correctly reflect the prices pharmacies are actually paying for prescription drugs. The complete text of the State Agency's comments is included as **APPENDIX 4**.



SAMPLE DESCRIPTION

Sample Objectives:

Develop an estimate of the extent of the discount below AWP of actual invoice prices to Medicaid pharmacies in West Virginia for brand name drugs and for generic drugs.

Population:

The sampling population was pharmacy providers participating in the Medicaid prescription drug program of the State Agency.

Sampling Frame:

The sampling frame was a listing of all pharmacy providers participating in the Medicaid prescription drug program.

Sample Design:

A sample of eight pharmacies was randomly selected from each of five strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) Each pharmacy was assigned a month from 1999 for which to provide invoices. All pharmacies were initially assigned a month from January through December in a method designed to provide a cross-section of the 12-month period. However, some pharmacies were permitted to submit invoices from other months as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eight pharmacies were selected from each stratum for a total of 40 pharmacies.

Source of Random Numbers:

We used OAS statistical sampling software to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that did not provide information. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

Estimation Methodology:

We used OAS statistical software to project the percentage difference between AWP and actual invoice prices for each stratum, as well as an overall percentage difference. The overall percentage difference excluded the non-traditional pharmacies. The projections were done separately for brand name drugs and generic drugs.

Other Evidence:

We obtained AWP from a pricing file received from the State of Florida.

WEST VIRGINIA SAMPLE RESULTS

	BRA	ND NAME	DRUGS –	AWP			
			Drug	San	nple	90 Pe Confider	
Category	Universe of Pharmacies	Sample Pharmacies	Prices Reviewed	Mean	Standard Deviation	Lower Limit	Upper Limit
RURAL-CHAIN	160	6	808	22.43	3.16	20.35	24.51
RURAL-INDEPENDENT	119	8	369	21.44	0.88	20.94	21.93
URBAN-CHAIN	137	8	1,132	21.88	2.64	20.39	23.36
URBAN-INDEPENDENT	62	7	419	19.99	2.69	18.41	21.56
NON-TRADITIONAL	18	7	228	23.86	16.69	15.75	31.97
OVERALL (EXCL. NON TRAD.)	478	29	2,728	21.71	0.52	20.86	22.56

GENERIC DRUGS – AWP

			Drug	San	nple	90 Pe Confider	
Category	Universe of Pharmacies	Sample Pharmacies	Prices Reviewed	Mean	Standard Deviation	Lower Limit	Upper Limit
RURAL-CHAIN	160	6	462	73.48	7.51	68.54	78.43
RURAL-INDEPENDENT	119	8	185	68.47	5.94	65.14	71.81
URBAN-CHAIN	137	8	689	70.29	10.52	64.35	76.22
URBAN-INDEPENDENT	62	7	171	54.94	21.99	42.06	67.82
NON-TRADITIONAL	18	8	152	61.38	14.82	54.95	67.80
OVERALL (EXCL. NON TRAD.)	478	29	1,507	68.92	1.84	65.90	71.93

NATIONWIDE SAMPLE RESULTS

	BRAND NAME	DRUGS – AW	/ P	
Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP (Point Estimate)
Rural-Chain	1,008	52	3,533	20.68
Rural-Independent	1,243	55	2,628	20.86
Urban-Chain	5,745	56	7,719	22.19
Urban-Independent	2,398	53	2,324	22.00
Non-Traditional	1,123	61	1,528	31.18
Overall (Excl. Non-Trad.)	10,394	216	16,204	21.84
		216 RUGS – AWP	16,204	21.84
		·	Drug Prices Reviewed	Percent Below AWP (Point Estimate)
Overall (Excl. Non-Trad.)	GENERIC D	RUGS – AWP	Drug Prices	Percent Below AWP
Overall (Excl. Non-Trad.) Category	GENERIC D Universe of Pharmacies	RUGS – AWP Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP (Point Estimate)
Overall (Excl. Non-Trad.) Category Rural-Chain	Universe of Pharmacies	RUGS – AWP Sample Pharmacies 52	Drug Prices Reviewed 2,073	Percent Below AWP (Point Estimate) 64.39
Category Rural-Chain Rural-Independent	Universe of Pharmacies 1,008 1,243	Sample Pharmacies 52 55	Drug Prices Reviewed 2,073 1,142	Percent Below AWP (Point Estimate) 64.39 66.64
Category Rural-Chain Rural-Independent Urban-Chain	Universe of Pharmacies 1,008 1,243 5,745	Sample Pharmacies 52 55 56	Drug Prices Reviewed 2,073 1,142 4,491	Percent Below AWP (Point Estimate) 64.39 66.64 66.97



STATE OF WEST VIRGINIA

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise Governor Bureau for Medical Services Commissioner's Office 350 Capitol Street - Room 251 Charleston, West Virginia 25301-3706 Phone: (304) 558-1700 - Fax: (304) 558-1451

Paul L. Nusbaum Secretary

October 18, 2001

Gordon L. Sato Regional Inspector General for Audit Services Office of Inspector General Office of Audit Services 1100 Commerce, Room 6B6 Dallas, Texas 75242

Dear Mr. Sato:

This responds to the draft report on the results of your review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the West Virginia Department of Health and Human Resources, Bureau for Medical Services.

We appreciate the effort that was made to produce this report and are grateful to William Shrigley and Paul Chesser who visited West Virginia and presented the results to us in a timely manner. We have reviewed the report and have no questions at this time. One suggestion that we would like to offer for future reviews is to either exclude or separate generic drugs which have a Federal Upper Limit (FUL) price from other generic drugs in the study. Since FUL drugs are selected by CMS for limited reimbursement due to their pricing advantage, and all generic drugs cannot be purchased at the deep discounts reflected on the FUL list, the cost of the other generic drugs may be under-reported. This could lead to underpayment to pharmacies for certain generic drugs if a general discount is used.

In the light of your findings, the Bureau is considering adjusting the discount of Average Wholesale Price (AWP) to more correctly reflect the prices pharmacies are actually paying for prescription drugs. We are expecting significant resistance from the pharmacies to price reductions, however, and in order to defend our actions, we would appreciate a copy of the database which you developed from information supplied by West Virginia pharmacies. In addition, we would also appreciate a copy of the invoices which you collected in order to make the cost estimates for our state. A concern being raised is the possibility of errors in the database. Having the invoices would be helpful to validate the data and would avoid having to repeat the process.

Again, please accept our appreciation for the work done to produce this report and for including West Virginia in the review. If you have questions or if I can be of any further assistance to you, please feel free to contact me.

Sincerely,

Mancy V. Atkins, MSN, RNC, NP

Commissioner

NVA:cs